91 remaining in the application. The International Preliminary Examination Report was based on Claims 1-5, 7-24, 26-39, 45-59, 61-67, 70-88, and 91.

Please cancel all claims, namely, Claims 1-5, 7-24, 26-39, 45-59, 61-67, 70-88, and 91.

Please add new Claims 92-140.

92. (new) A formulation comprising FSH or a FSH variant, containing an alpha and beta subunit, and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof in an aqueous diluent.

93. (new) The formulation of Claim 92, wherein the preservative is phenol, m-cresol, chlorocresol, or a mixture thereof.

94. (new) The formulation of Claim 93, wherein the concentration of FSH or a FSH variant is about 1.0 µg/ml to about 50 mg/ml.

95. (new) The formulation of Claim 94, wherein the concentration of FSH or FSH variant is about 5.0 µg/mL to 2 mg/mL.

96. (new) The formulation of Claim 95, wherein the concentration of FSH or FSH variant is 50 µg/mL to about 200 µg/mL.

97. (new) The formulation of Claim 96, further comprising an isotonicity agent.

98. (new) The formulation of Claim 97, wherein the isotonicity agent is sodium chloride.

99. (new) The formulation of Claim 97, further comprising a physiologically acceptable buffer.

100. (new) The formulation of Clam 98, wherein the buffer agent is sodium phosphate.

101. (new) The formulation of Claim 100 comprising human FSH.

102. (new) The formulation of Claim 100 comprising an FSH variant of the formula:

α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST

CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV

YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

103. (new) The formulation of Claim 97 comprising human FSH.

104. (new) The formulation of Claim 97 comprising an FSH variant of the formula:

α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

105. (new) The formulation of Claim 93 comprising human FSH.

106. (new) The formulation of Claim 93 comprising an FSH variant of the formula:

α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

107. (new) The formulation of Claim 92, wherein said FSH or a FSH variant is at least one compound selected from the group consisting of:

(a): α-subunit:(SEQ ID NO:1)

FPDGEFTMQGCPECKLKENKYFSKPDAPIYQCMGCCFSRAYPTPARSKKTMLVPKNIT
SEATCCVAKAFTKATVMGNVRVENHTECHCSTCYYHKS

β-subunit:(SEQ ID NO:2)

RSCELTNITITVEKEECGFCISINTTWCAGYCYTRDLVYRDPARPNIQKTCTFKELVY
ETVKVPGCAHHADSLYTYPVATECHCSKCDSDSTDCTVRGLGPSYCSFREIKE

(b):α-subunit:(SEQ ID NO:3)

FPDGEFTTQDCPECKLRENKYFFKLGVPIYQCKGCCFSRAYPTPARSRKTMLVPKNIT
SESTCCVAKAFIRVTVMGNIKLENHTQCYCSTCYHHKI

β-subunit:(SEQ ID NO:4)

NSCELTNITIAVEKEGCGFCITINTTWCAGYCYTRDLVYKDPARPNIQKTCTFKELVY
ETVKVPGCAHHADSLYTYPVATACHCGKCNSDSTDCTVRGLGPSYCSFGDMKE

(c):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:6)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEMKE

(d):α-subunit:(SEQ ID NO:7)

FPDGEFTMQGCPECKLKENKYFSKLGAPIYQCMGCCFSRAYPTPARSKKTMLVPKNIT
SEATCCVAKAFTKATVMGNARVENHTECHCSTCYYHKS

β-subunit:(SEQ ID NO:8)

NSCELTNITITVEKEECNFCISINTTWCAGYCYTRDLVYKDPARPNIQKTCTFKELVY
ETVKVPGCAHHADSLYTYPVATECHCGKCDSDSTDCTVRGLGPSYCSFSEMKE

(e):α-subunit:(SEQ ID NO:9)

FPDGEFTMQGCPECKLKENKYFSKPDAPIYQCMGCCFSRAYPTPARSKKTMLVPKNIT
SEATCCVAKAFTKATVMGNVRVENHTECHCSTCYYHKS

β-subunit:(SEQ ID NO:10)

RSCELTNITITVEKEECSFCISINTTWCAGYCYTRDLVYKDPARPNIQKACTFKELVY
ETVKVPGCAHHADSLYTYPVATECHCGKCDRDSTDCTVRGLGPSYCSFSDIRE

(f):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE

(g):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:12)

Replaced by Amendment A / cont.

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEM

(h):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:13)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEMK

108. (new) The formulation of Claim 107 comprising human FSH.

109. (new) The formulation of Claim 107 comprising comprising an FSH variant of the formula:

(f):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

110. (new) A method of treating infertility which comprises administering to a patient in need thereof a formulation according to Claim 92.

111. (new) The method of Claim 110, wherein said patient is selected from the group consisting of a human, sheep, cow, pig, horse, and rabbit.

112. (new) A process for preparing the formulation of Claim 92, comprising admixing FSH or a FSH variant and a preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate, thimerosal, and mixtures thereof, in an aqueous diluent.

113. (new) An article of manufacture for human pharmaceutical use, comprising packaging material and a vial comprising the formulation of Claim 92, wherein said packaging material comprises a label which indicates that said solution may be held over a period of 24 hours or greater.

114. (new) The article of Claim 113, wherein the vial is a glass container having a stopper for multi-use administration.

115. (new) The article of Claim 113, wherein the vial is a pen-injector device.

116. (new) An article of manufacture, comprising packaging material, a first vial comprising lyophilized FSH or a FSH variant, containing an alpha and beta subunit, and a second vial comprising a preservative solution, wherein said packaging material comprises a label which instructs a patient to reconstitute the said lyophilized FSH or a FSH variant in the preservative solution for use over a period of 24 hours or greater, and wherein reconstituting produces the formulation of Claim 1.

117. (new) The article of manufacture of Claim 116, wherein said first vial and said second vial are embodied in a pen-injector device.

118. (new) A stable formulation comprising at least one FSH or a FSH variant, containing an alpha and beta subunit, and phosphate buffer containing saline or a salt, wherein said FSH or a FSH variant comprises at least 90% FSH or a FSH variant dimers after 60 days at 23°C.

119. (new) The formulation of Claim 118, wherein the concentration of said FSH or a FSH variant is about 1.0 µg/ml to about 50 mg/ml.

120. (new) The formulation of Claim 119, wherein the concentration of FSH or FSH variant is about 5.0 µg/mL to 2 mg/mL.

121. (new) The formulation of Claim 120, wherein the concentration of FSH or FSH variant is 50 µg/mL to about 200 µg/mL.

122. (new) The formulation of Claim 121, further comprising an isotonicity agent.

123. (new) The formulation of Claim 122, wherein the buffer is phosphate buffered saline.

124. (new) The formulation of Claim 123, comprising human FSH.

125. (new) The formulation of Claim 123, comprising an FSH variant of the formula:

α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST

CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV

YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

126. (new) The formulation of Claim 118, further comprising an isotonicity agent.

127. (new) The formulation of Claim 126, wherein the buffer is phosphate buffered saline.

128. (new) The formulation of Claim 127, comprising human FSH.

129. (new) The formulation of Claim 127, comprising an FSH variant of the formula:

α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST

CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV

YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

130. (new) The formulation of Claim 118 comprising human FSH.

131. (new) The formulation of Claim 118 comprising an FSH variant of the formula:

α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELV
YETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE.

132. (new) The formulation of Claim 118, wherein said FSH or a FSH variant is at least one compound selected from the group consisting of:

(a): α-subunit:(SEQ ID NO:1)

FPDGEFTMQGCPECKLKENKYFSKPDAPIYQCMGCCFSRAYPTPARSKKTMLVPKNIT
SEATCCVAKAFTKATVMGNVRVENHTECHCSTCYYHKS

β-subunit:(SEQ ID NO:2)

RSCELTNITITVEKEECGFCISINTTWCAGYCYTRDLVYRDPARPNIQKTCTFKELVY
ETVKVPGCAHHADSLYTYPVATECHCSKCDSDSTDCTVRGLGPSYCSFREIKE

(b):α-subunit:(SEQ ID NO:3)

FPDGEFTTQDCPECKLRENKYFFKLGVPIYQCKGCCFSRAYPTPARSRKTMLVPKNIT
SESTCCVAKAFIRVTVMGNIKLENHTQCYCSTCYHHKI

β-subunit:(SEQ ID NO:4)

NSCELTNITIAVEKEGCGFCITINTTWCAGYCYTRDLVYKDPARPNIQKTCTFKELVY
ETVKVPGCAHHADSLYTYPVATACHCGKCNSDSTDCTVRGLGPSYCSFGDMKE

(c):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:6)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEMKE

(d):α-subunit:(SEQ ID NO:7)

FPDGEFTMQGCPECKLKENKYFSKLGAPIYQCMGCCFSRAYPTPARSKKTMLVPKNIT
SEATCCVAKAFTKATVMGNARVENHTECHCSTCYYHKS

β-subunit:(SEQ ID NO:8)

NSCELTNITITVEKEECNFCISINTTWCAGYCYTRDLVYKDPARPNIQKTCTFKELVY
ETVKVPGCAHHADSLYTYPVATECHCGKCDSDSTDCTVRGLGPSYCSFSEMKE

(e):α-subunit:(SEQ ID NO:9)

FPDGEFTMQGCPECKLKENKYFSKPDAPIYQCMGCCFSRAYPTPARSKKTMLVPKNIT
SEATCCVAKAFTKATVMGNVRVENHTECHCSTCYYHKS

β-subunit:(SEQ ID NO:10)

RSCELTNITITVEKEECSFCISINTTWCAGYCYTRDLVYKDPARPNIQKACTFKELVY
ETVKVPGCAHHADSLYTYPVATECHCGKCDRDSTDCTVRGLGPSYCSFSDIRE

(f):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:11)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGE

(g):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:12)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEM

(h):α-subunit:(SEQ ID NO:5)

APDVQDCPECTLQENPFFSQPGAPILQCMGCCFSRAYPTPLRSKKTMLVQKNVTSEST
CCVAKSYNRVTVMGGFKVENHTACHCSTCYYHKS

β-subunit:(SEQ ID NO:13)

NSCELTNITIAIEKEECRFCISINTTWCAGYCYTRDLVYKDPARPKIQKTCTFKELVY
ETVRVPGCAHHADSLYTYPVATQCHCGKCDSDSTDCTVRGLGPSYCSFGEMK

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133. (new) A method of treating infertility which comprises administering to a patient in need thereof a formulation according to Claim 118.

134. (new) The method of Claim 133, wherein said patient is selected from the group consisting of a human, sheep, cow, pig, horse, and rabbit.

135. (new) A process for preparing the formulation of Claim 118, comprising admixing FSH or a FSH variant with a phosphate buffer containing saline or a salt.

136. (new) An article of manufacture for pharmaceutical use, comprising packaging material and a vial comprising the formulation of Claim 118, wherein said packaging material comprises a label which indicates that such solution is suitable for use over a period of 24 hours or greater.

137. (new) The article of manufacture of Claim 136, wherein said vial is a glass container having a stopper for multi-use administration.

138. (new) The article of manufacture of Claim 136, wherein said vial is a pen-injector device.

139. (new) An article of manufacture, comprising packaging material, a first vial comprising lyophilized FSH or a FSH variant, containing an alpha and beta subunit, and a second vial comprising a preservative solution, wherein said packaging material comprises a label which instructs a patient